Butler, Jennie C

From: Paul Orum [paul_orum@yahoo.com]
Sent: Monday, April 24, 2000 5:37 PM
To: fdadockets@oc.fda.gov
Cc: fdadocket@oc.fda.gov
Subject: To docket 97N-0436 - bottled water

SDWA-Bottled Water RTK Comment...

Below are comments to the FDA docket indicated in text format (without footnotes) and as an attachment (with footnotes). A hard copy will be sent by regular mail.

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April 24, 2000

Dockets Management Branch (HFA-305)
Docket Number 97N-0436
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: FDA Draft Study Report; Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water (Docket 97N-0436).

Hundreds of thousands of people in the United States depend on bottled water as their sole drinking water source, either because they live in an area whose drinking water source has been contaminated, or because they belong to a vulnerable population, including some children, elderly, or immunocompromised individuals. Therefore the public has a right to know the same information about their bottled water as individuals on a public water supply regulated by the U.S. Environmental Protection Agency. We support reporting guidance that requires bottled water suppliers and the Food and Drug Administration (FDA) to clearly list complete and detailed information about contaminants in bottled water.

We feel that bottled water suppliers and the FDA can best accomplish the above-stated goals through an integrated system that uses labels corresponding to EPA's consumer confidence reports, with added vital information that relates specifically to bottled water (see below). We feel that an integrated FDA web site is a necessary addition to this information integration and clarification process. Full and detailed information will enhance consumer choice, support safe industry practices, and encourage pollution prevention and source-water protection.

We believe it will be a reasonable economic burden on the bottled water industry to provide the information listed below, given legitimate consumer health and right-to-know concerns, given current advertising, marketing and labeling design budgets, and given the industry's claims that their water is clean and safe. If these statements are true then labels that list only detected contaminants in the contaminant chart should be neither cumbersome nor burdensome. Information on non-detected contaminants is also

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important to make available through the company and an FDA web site, but not the product label. For most elements and circumstances, labels would provide yearly information, similar to a consumer confidence report.

We urge FDA to require the following information on bottled water labels:

 The level, expressed in whole numbers, of any contaminant found in the water at a level in excess of a health goal , plus the fluoride level and sodium level;
 The health goal and allowable level for those contaminants found in the water and noted above, in the same units;
 A statement as to whether the bottler is in substantial compliance with state and federal regulations (based upon an annual certification sent to the state and FDA and not disagreed with in writing by either), and if not, what violations occurred;
 A one-sentence lay person-readable summary of the health effects associated with any contaminant found at a level in excess of a health goal (taken from model language written by FDA and EPA);
 A simplified restatement of the EPA/CDC advice to immunocompromised consumers about the types of bottled water treatment necessary to avoid cryptosporidium contamination, and whether the bottled water meets those criteria;
 The specific water source (e.g. "Philadelphia Public Water System") and treatment (e.g. "reverse osmosis and ozonation");
 An FDA toll free number for consumers to obtain more information (or a referral to EPA's drinking water hotline);
 The bottler's street address, toll free phone number, and web and email address (if any) for further questions.

The FDA feasibility study neglected an important and necessary communication option: a uniform, standardized national web site of CCR-type contaminant information (as expressed in the points above) that is operated by and under the control of the FDA. This FDA web site should list all bottled water companies, each with a national corporate identifier, and the information listed above in one site for ready comparison between companies. This integrated FDA web site would not replace the more critical function of a product label, but would vitally enhance it. Such a uniform national FDA web site would reduce burdens on bottled water companies by providing direct information at very low cost to some of the customers who otherwise would require assistance by phone or other means directly from the company. In addition, the integrated FDA web site would help ensure that water customers in fact obtain full information.

Most consumers evaluate products and make final purchasing decisions at the store while buying the product. While individual company Internet sites and toll free customer numbers are important additions to direct bottle labeling and an integrated FDA web site, they will not provide substantial numbers of consumers with important information where it matters most -- the point of sale. Direct product labeling is the backbone of community right-to-know about bottled water. We believe such labeling is a feasible and important public health safeguard that should be supplemented with full CCR-type information available

both directly from the company and through a uniform national FDA web site.

Sincerely,

Lisa Mosca
Coordinator,
Working Group on Community Right-to-Know

Grant Cope
Staff Attorney,
U.S. Public Interest Research Group

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We believe it will be a reasonable economic burden on the bottled water industry to provide the information listed below, given legitimate consumer health and right-to-know concerns, given current advertising, marketing and labeling design budgets, and given the industry's claims that their water is clean and safe. If these statements are true then labels that list only detected

contaminants in the contaminant chart should be neither cumbersome nor burdensome. Information on non-detected contaminants *is* also important to make available through the company and an FDA web site, but *not* the product label. For most elements and circumstances, labels would provide yearly information, similar to a consumer confidence report.

We urge FDA to require the following information on bottled water labels:

- The level, expressed in whole numbers, of any contaminant found in the water at a level in excess of a health goal[1], plus the fluoride level and sodium level;
- The health goal and allowable level for those contaminants found in the water and noted above, in the same units;
- A statement as to whether the bottler is in substantial compliance with state and federal regulations (based upon an annual certification sent to the state and FDA and not disagreed with in writing by either), and if not, what violations occurred;
- A one-sentence lay person-readable summary of the health effects associated with any contaminant found at a level in excess of a health goal (taken from model language written by FDA and EPA);
- A simplified restatement of the EPA/CDC advice to immunocompromised consumers about the types of bottled water treatment necessary to avoid *cryptosporidium* contamination, and whether the bottled water meets those criteria;
- The specific water source (e.g. "Philadelphia Public Water System") and treatment (e.g. "reverse osmosis and ozonation");
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The FDA feasibility study neglected an important and necessary communication option: a uniform, standardized national web site of CCR-type contaminant information (as expressed in the points above) that is

[1] The Term "health goal" refers to an EPA Maximum Contaminant Level Goal (MCLG, see SDWA Sec. 1412(b)(4)(A)), if any, or, if there is no MCLG, the lowest EPA Health Advisory Level (HAL, see SDWA Sec. 1412(b)(1)(F)), or if there is no MCLG or HAL, the lowest EPA human health-based water quality criteria for that contaminant (see Clean Water Act Secs. 303-304). For contaminants with an MCL but no MCLG, it is particularly important for health-based water quality criteria to be noted on the label (until an MCLG is published), as such standards have not been revised since 1962 and thus do not reflect up to date science.

operated by and under the control of the FDA. This FDA web site should list all bottled water companies, each with a national corporate identifier, and the information listed above in one site for ready comparison between companies. This integrated FDA web site would not replace the more critical function of a product label, but would vitally enhance it. Such a uniform national FDA web site would *reduce* burdens on bottled water companies by providing direct information at very low cost to *some* of the customers who otherwise would require assistance by phone or other means directly from the company. In addition, the integrated FDA web site would help ensure that water customers in fact obtain full information.

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Sincerely,

Lisa Mosca
Coordinator,
Working Group on Community Right-to-Know[2]

Grant Cope
Staff Attorney,
U.S. Public Interest Research Group[3]

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[2] The Working Group on Community Right-to-Know is an affiliation of some 1,500 public interest environmental organizations in the United States. Since 1987, the Working Group has promoted effective development of U.S. community right-to-know laws, including disclosure requirements for both toxic pollution and chemical accidents.

[3] U.S. PIRG is the national office for the State Public Interest Research Groups. The State PIRGs are non-profit, non-partisan consumer and environmental advocacy groups active across the country.